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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/306,006	05/06/1999	ANDREAS WERNER SUPERSAXO	NB/2-21551/A	2914

324 7590 03/26/2002

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/306,006

Applicant(s)

SUPERSAXO ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,6,10,15-21,24,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,6,10,15-21,24,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on January 8, 2002 has been entered. Claims 2, 6, 10, 15-21, 24, 28-29 are pending in this application.

Response to Amendment

Any rejection that is not addressed in this Office action is obviated in view of the claim amendments, Applicant's arguments and the filing of a Terminal Disclaimer.

The Declaration under 37 CFR 1.132 filed on March 22, 2001 has been previously considered in Paper No. 14. Upon reconsideration and in view of the newly amended claims, the declaration is found sufficient to overcome the rejection of claims 2, 6, 10, 15-21, 28-29 under 35 USC 103 (a) based upon Weder US Patent 5,997,88.

New Grounds of Rejection

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 6, 10, 15-21, 24, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yiv et al US Patent 6,245,349 in view of Weder WO 96/37192.

The instant claims are now directed to aqueous nanodispersion formulations and methods of preparing them wherein the formulations consisting essentially of (a) 0.1-30% by weight of phospholipid (b) 1-50% by weight of polyoxyethylene co emulsifier (c) 0.1-80% by weight of a lipophilic component which comprise a natural or synthetic or a partially synthetic C₄- C₁₈ triglyceride and a lipophilic active agent in which aqueous nanodispersion, any pharmaceutically active agent is lipophilic and the active agent is

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always present in component (c), (d) 0.63-1.42% by weight ethanol, wherein the sum of (a), (b), (c) and (d) is 100% weight, and the formulation further contains a water phase.

Yiv et al disclose drug delivery compositions comprising particles having a size below about 50 nm diameter, and further comprising a lipophilic drug, a phospholipid (Centrophase 31), a polyoxyethylene co emulsifier (Tween 80 which is polyoxyethylene (20) sorbitan monoloeate), and a lipophilic component comprising triglycerides or propylene glycol diester oils having C₆ to C₁₄ for the total of 100% weight, which can further be diluted with water to form an o/w emulsion (see col 5, lines 5-10, 50-65; col 6, lines 5-20, 38-65; col 9, lines 10, lines 14-60, tables 1.3, 3.1, 5.1; col 15-16, claims 1-8). The concentrations of each of Yiv's components falls within the instantly claimed ranges (see tables 1.3, 3.1, 5.1; claims 1-8). Yiv also uses methods ~~of~~^s which do not need for high shear mixing equipments (see col 8, lines 20-28, col 10, lines 15-25). Yiv further teaches that lower alcohols such as ethanol may be used in his compositions (col 7, lines 10-14). However, Yiv fails to specifically disclose a compositions containing ethanol.

'192 patent primarily teaches similar type of nanodispersion compositions comprising phospholipid, polyoxyethylene, a lipophilic component, ethanol, a triglyceride, and a therapeutic agent. '192 also provides that the use of triglycerides improves stability and solubility of lipophilic drug in an aqueous emulsion system is conventional (see entire document, claims 1-5). '192 further teaches that it is well within purview of an ordinary skill in the art to select a suitable carrier system for the intended pharmaceutical and cosmetic use. Accordingly, using ethanol to form an aqueous

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dispersion is conventional and dependent on the utility of the formulation (see page 13, 19-23).

Consequently, even though Yiv fails to use ethanol in his composition it would have been obvious to one of ordinary skill in the art at the time of invention to add ethanol into Yiv's carrier system as suggested by Yiv itself and as taught by '192, because the ordinary skill in the art would have had a reasonable expectation of success to enhance the delivery of Yiv's active agent to any specific tissue, such as dermal tissue, when adding adequate amount of ethanol to Yiv's carrier system.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, because it has modified the scope of the pending claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

ss
March 19, 2002